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Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, rm. 1061
Rockville, MD 20852

Regarding: Docket No. 99D - 0302
Compliance Guidance: The Mammography Quality Standards Act Final Regulations Document #2

Following are comments on the FDA's draft compliance guidance document #2 for the MQSA final regulations. Included is an excerpt from the Compliance Guidance Document followed by a Comment to FDA.

Equipment

21 CFR 900.12(b)(4)(iii)
Systems used for magnification procedures shall be capable of operation with the grid removed from between the source and image receptor.

Question: We perform magnification using only the 18 X 24 cm image receptor. Do we have to show that all our other image receptor sizes also meet the magnification requirements?

Answer: No. .... The third requirement relating to the system resolution under 900.12(e)(5)(iii) is not dependent on the image receptor size.

Comment to FDA:

Stating that the requirement on system resolution is not dependent on the image receptor size leads us to infer that FDA is suggesting that the image receptor, the cassette, the Bucky, and the grid do not play a role in determining the system resolution. This may be a result of the content of 900.12(e)(5)(iii), which suggests that only the focal spot is responsible for the system resolution. As one example, poor screen-film contact may play a greater role in system resolution than the focal spot; and the quality of the screen-film contact may well be different for the different sizes of image receptors. We suggest that FDA reword the last sentence of the answer to emphasize that all elements of an imaging chain have an impact on system resolution and this includes the various sizes of image receptors and their associated equipment.

21 CFR 900.12(b)(8)(ii)(B)
Except as provided in paragraph (b)(8)(ii)(C) of this section, the compression paddle shall be flat and parallel to the breast support table and shall not deflect from parallel by more than 1.0 cm at any point on the surface of the compression paddle when compression is applied.

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Question: Who is responsible for performing the compression paddle deflection test? How often should this test be performed and by what method?

Answer: ... One acceptable method for performing the compression paddle deflection test is:

...

3. ... Examples of test objects include: compressible foam materials (e.g. T-200 Minicel foam (10 X 14 cm for the 18 X 24 cm paddle and 14 X 22 cm for the 24 X 30 cm paddle, thickness of 4 to 6 cm) or tennis or rubber balls taped together in the shaped of an equilateral triangle (3 balls for the 18 X 24 cm paddle and 6 balls for the 24 X 30 cm paddle)
4. Apply a compression force of 111 newtons (25 pounds).
5. Measure the distance of each corner of the paddle from the support plate.
6. Subtract the smallest distance from the largest distance to determine the deflection. The difference must be 1.0 cm or less to pass the test.

Comment to FDA:

While we are in general agreement with much of the method presented here, we recommend, based on published literature and measurements made by manufacturers, that the overall dimensions of the test object for the 18 x 24 paddle be 10 cm x 18 cm, not 10 cm x 14 cm.

In regard to the test objects recommended for this test (step 3), we support the use of the foam block test object, which is partially described in the Compliance Guidance Document. The size and material were chosen to provide some reasonable approximation to the human compressed breast. The material has also been found to be stable and resistant to chemicals that might be found in a clinical environment. Hence, when used to evaluate the consistency of performance of the compression paddle, the user has some confidence that the test tool itself is also consistent.

In contrast, we do not see any similar attributes for the test object consisting of "tennis or rubber balls taped together in the shaped of an equilateral triangle." Tennis balls are notorious for their rapid change of compressibility with time after they are removed from the can. Hence, there is no consistency of the test object. There is no specification of the size or compressibility of the rubber balls to be used, hence there is no apparent intent to make this test object in anyway clinically relevant. Finally, although the semi-circular shape of the test objects suggested to the FDA by several manufacturers (and omitted from the text of the Compliance Guidance Document) may be only an approximation of the shape of the human, compressed breast, we believe that it is a far better approximation than an equilateral triangle constructed of spheres.

We strongly recommend that FDA withdraw the recommendation to use test objects that have not been demonstrated to be in any way relevant to the clinical situation under evaluation.

We agree with the recommendation in step 4 to apply moderate compression and not the maximum possible compression force. If the intent is to identify paddles with loose mountings or defective parts, moderate compression should be sufficient. High compression force leads to deformation of the plastic which may not be undesirable in the clinical application.

Similarly we support step 5, measurement of the deflection at the corners of the paddle. This procedure should identify defective paddles without adding undue complexity to the measurement or motivating the development of non-deformable paddle designs which may result in increased patient discomfort.

In regard to the limitation of the deflection to less than 1.0 cm (step 6), we suggest that FDA add a statement such as " ... or the deflection specified by the manufacturer of the compression paddle if the paddle has not been designed to be flat and parallel to the breast support table."

Quality Control (QC) Tests - General

Question: When performing a physics survey or equipment evaluation on a unit with multiple target/filter combinations, what tests or measurements must be performed for each combination?

Answer: For a unit with multiple target/filter combinations, the following tests must be performed for each clinically used target/filter combination:

- Focal spot condition (for different target materials only)
- X-ray field/light field/image receptor/compression paddle alignment (for different target materials only)
- Beam quality and half-value layer
- Automatic exposure control performance
- System artifacts

Comment to FDA:

We agree with the list of tests identified as those that should be performed for multiple target/filter combinations. We would suggest, in the interest of generality, that in the two parenthetical statements the words "materials" be changed to "tracks." To provide multiple target materials, present technology uses separate filaments and spatially separated anode tracks giving rise to focal spots with different characteristics and x-ray beams that are shifted one from another. Future technology may allow changing target materials without changing the electron optics of the x-ray tube or the beam geometry.

QC Tests - Annual

21 CFR 900.12(e)(5)
(iii) *Focal spot condition. Until October 28, 2002, focal spot condition shall be evaluated either by determining system resolution or by measuring focal spot dimensions. After October 28, 2002, facilities shall evaluate focal spot condition only by determining the system resolution.*

Question: Does the condition of the focal spot have to be measured at all possible magnification values?

Answer: The facility is required to evaluate the focal spot condition only for the clinically used magnification factor as close to 1.5 as can be achieved with the system.

Comment to FDA:

We strongly agree with the FDA's proposal to only require that the system resolution be evaluated at the clinically used magnification factor as close to 1.5 as can be achieved with the system. There is no

scientific evidence supporting the 11 and 13 lp/mm requirement and published research demonstrates a lack of correlation between limiting resolution and image quality for high magnifications. (J. Law, "The influence of focal spot size on image resolution and test phantom scores in mammography," *Brit. Jnl of Radiology,* **66**, 441-446, 1993.) We recommend that the FDA go further in this regard to educate the mammography community that in large part the benefit to be gained from magnification imaging is due to the improvement of signal-to-noise ratio and not limiting resolution and that application of the 11 and 13 lp/mm limits has no scientific basis. (G. T. Barnes, "Tube Potential, Focal Spot, Radiation Output and HVL Measurements on Screen-Film Mammography Units," in *Screen Film Mammography: Imaging Considerations and Medical Physics Responsibilities*, G. T. Barnes, and G. D. Frey, eds., Medical Physics Pub., Madison, WI, 1991, pp. 86-87. K. Doi, "Advantages of Magnification Radiography," in *Breast Carcinoma: The Radiologist's Expanded Role*, W. W. Logan, John Wiley and Sons, New York, 1977, pp. 83-92.) Facilities should not be led to infer (or worse yet be directly advised) that high levels of magnification should be avoided because of an inability of a system to meet an arbitrary and scientifically unsupported spatial resolution limit.

Question: What is meant by the term "focal spot condition" and how does it relate to "system resolution"?

Answer: ... In many cases, the focal spot will not be the cause of the system resolution test failure and other factors in the imaging chain will have to be evaluated to identify the actual problem.

Comment to FDA:

We strongly agree with FDA's efforts here to point out that many other factors may affect system resolution besides the size of the focal spot.

Question: Where in the x-ray field should focal spot size be measured?

Answer: ... Facilities may follow the manufacturer's recommendation or physicist's judgment or any appropriate QC manual in meeting the focal spot tolerance limit listed in the regulation.

Comment to FDA:

Although no reference is cited, the values in Table 1 of the regulation are identical with the values given in NEMA XR5-1992 and IEC 336/1993. Manufacturers specify that focal spots will meet these values on the reference axes identified by the manufacturers. We recommend that the FDA clarify this situation and not lead facilities to expect that they can achieve such a focal spot size at any location in the x-ray field.

Thank you for your consideration of these comments.

Sincerely,

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